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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ANN LEWANDOWSKI and ROBERT GREGORY, on their own behalf, on behalf of all others similarly situated, and on behalf of the Johnson & Johnson Group Health Plan and its component plans, Plaintiffs, v. JOHNSON & JOHNSON and THE PENSION & BENEFITS COMMITTEE OF JOHNSON & JOHNSON, Defendants.	Case No. 3:24-cv-00671-ZNQ-RLS **ORAL ARGUMENT REQUESTED**

BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS COUNTS ONE AND TWO OF THE SECOND AMENDED COMPLAINT

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INTRODUCTION

After extensive briefing, this Court dismissed the core claims in the First Amended Complaint, finding that Plaintiff Ann Lewandowski lacked standing under Article III to assert them. Since then, another district court has dismissed the same novel ERISA claims, also on standing grounds. *See Navarro v. Wells Fargo & Co.*, No. 24-cv-3043, 2025 WL 897717 (D. Minn. Mar. 24, 2025).

In the Second Amended Complaint, Lewandowski adds allegations contending that by virtue of the actions of a third party, she paid approximately $980—rather than about $770—of the more than $200,000 in medical expenses the J&J Plan paid on her behalf in a single year. She contends that in 2023, a third party reimbursed her for a portion of some of the copayments she made toward her $3,500 out-of-pocket maximum, and that Defendants somehow prevented her from receiving an even greater discount. The Second Amended Complaint also adds a new Plaintiff who complains that he paid $20, rather than the roughly $10 he says he should have been charged, for a single generic drug. But these changes do nothing to cure the standing defects that permeate Plaintiffs' novel theory, and both Plaintiffs lack standing for the reasons articulated in this Court's earlier ruling and in *Navarro*: Their theory of harm depends not on concrete, redressable injury, but instead on layers of speculation about hoped-for changes in healthcare premiums and prices of certain prescription drugs, most of which Plaintiffs do not allege they

ever purchased. Plaintiffs' lack of standing requires the dismissal of Counts One and Two.

Even if Plaintiffs had standing, Counts One and Two, both of which assert claims for breach of fiduciary duty under ERISA, should be dismissed under Rule 12(b)(6). To state these claims, Plaintiffs must adequately plead that Defendants' process for choosing a pharmacy benefit manager and negotiating the cost of the totality of covered drugs was imprudent. At a minimum, this requires allegations that the Plan's *overall* costs—not cherry-picked examples of allegedly overpriced generic drugs, out of the thousands of drugs and healthcare services covered by the Plan—were excessive compared to meaningful benchmarks. But the Second Amended Complaint contains no allegations about Defendants' process, no allegations about the Plan's overall costs, and no allegations of a meaningful benchmark. As a result, even if Plaintiffs have standing, Counts One and Two should be dismissed with prejudice.

BACKGROUND

A. The Plan.

Johnson & Johnson is a medicine and medical technology company with more than 130,000 employees worldwide. Through the Plan, it provides its employees, retirees, and their family members with a generous suite of medical,

vision, dental, and prescription drug benefits. Dkt. 74 (Second Amended Complaint, or "SAC") ¶¶ 14–15; Ex. A, Plan Doc. §§ 1.02–03 & Schedule A.[1]

The Plan is self-funded. Instead of paying premiums to an insurance company, J&J directly bears the lion's share of the costs of medical and prescription drug expenditures on behalf of its employees and retirees. *See* SAC ¶¶ 16–17; Ex. A, Plan Doc. § 4.02. While Plan participants pay premiums, deductibles, and copays, those contributions pale in comparison with J&J's: In 2022, J&J paid more than $800 million in Plan costs, while participants paid just $148 million. *See* SAC ¶¶ 16, 196; Ex. B, Summary Annual Rpt. at 1. Because J&J pays so much of the Plan's costs, it has a strong incentive to negotiate the best deal it can for the overall package of covered benefits, including prescription drugs.

B. The prescription drug benefit.

To meet the needs of different participants, the Plan offers different levels of coverage with different levels of premiums. Each option covers both medical services and prescription drugs, including benefits that allow participants to obtain virtually any prescription drug approved for use in the United States. *See generally, e.g.*, Ex. C, Premier HSA Medical Plan Details Supplement.

[1] The Plan documents (Exhibits A–D) are judicially noticeable because the Second Amended Complaint "expressly references and relies upon the Plan." *Lipani v. Aetna Life Ins. Co.*, 2023 WL 3092197, at *6 n.3 (D.N.J. Apr. 26, 2023).

Under the Premier HSA Medical Plan option—the one chosen by Ms. Lewandowski—a participant must pay a deductible for most covered services. *Id.* at 4. The out-of-pocket costs of medical services and prescription drugs count toward the deductible. *Id.* Applicable law and IRS guidance set floors for the deductibles used by plans like the Premier HSA Plan, and the deductible under J&J's Premier HSA Plan is the lowest permitted by law. Ex. D, Decl. ¶ 6(a).[2]

Once a participant has met her annual deductible, the participant and the Plan split the costs of services, a practice known as "co-insurance." If a participant obtains a drug at an in-network retail pharmacy, she typically pays 20% of the cost of the drug, up to a maximum of $125 per prescription for a 30-day supply. Ex. E, Prescription Drug Coverage Details Supplement at 7. The Plan pays any remaining amount. *Id.* As a result, a participant's responsibility for any given prescription drug is generally capped at $125 a month. *See id.* at 6–9.

The Plan also sets an out-of-pocket maximum that limits the total cost-sharing a participant can bear for in-network services in any given year. *See id.* at 6–7; Ex. C, Premier HSA Medical Plan Details Supplement at 10–11. After a participant meets the deductible and has reached the applicable out-of-pocket maximum for in-network services, the participant pays nothing (and the Plan pays

[2] The Court can consider this declaration for purposes of addressing whether the case should be dismissed under Rule 12(b)(1) for lack of standing. *See, e.g.*, *Sharifi v. Township of E. Windsor*, 2023 WL 2182003, at *3 (D.N.J. Feb. 23, 2023).

the entire amount) for covered expenses, including prescription drugs, for the rest of the year. *See* Ex. C, Premier HSA Medical Plan Details Supplement at 10.

Each year Ms. Lewandowski was a participant (2022–2024), her maximum out-of-pocket amount was $3,500. Ex. D, Decl. ¶ 6(d). Plaintiff Gregory, who retired from J&J in 2020, was eligible for retiree medical coverage and chose coverage for his family with a maximum out-of-pocket amount of $12,000. *Id.* ¶¶ 14(d), 15(d).

C. The role of ESI.

To administer the prescription drug portion of the Plan, J&J contracted with Express Scripts, Inc. ("ESI"), a pharmacy benefit manager ("PBM"). SAC ¶ 94. ESI negotiates drug prices with pharmacies, secures rebates from drug manufacturers, and processes claims for prescription drugs. *See id.* ¶ 38. When a participant obtains a prescription, ESI pays the pharmacy (minus any participant-paid amount), and then later receives payment from the Plan. *See id.* ¶¶ 32–33, 38.

The Plan's drug costs are negotiated between J&J and ESI. *See id.* ¶ 42. As part of these negotiations, plan sponsors and PBMs often negotiate limits on the amount a plan will pay for categories of drugs based on a benchmark price, such as the Average Wholesale Price, or AWP. *Id.* ¶¶ 43–44. To use Plaintiffs' examples, plan fiduciaries and ESI might negotiate prices equal to "AWP minus 85%" for

generic drugs, "AWP minus 20%" for branded drugs, and "AWP minus 15%" for specialty drugs. *Id.* ¶ 45.

D. Plaintiffs' participation in the Plan.

Each year Ms. Lewandowski participated in the Plan, she chose the Premier HSA Medical Plan option. Ex. D, Decl. ¶ 5. Mr. Gregory started participating in the Plan as a retiree in 2020. *Id.* ¶ 12. He selected the Aetna HRA Plan option from 2020 to 2024, then switched to the Aetna PPO Plan option in 2025. *Id.* ¶ 13.

Plaintiffs do not allege that they were denied any benefits under the Plan or that they had to pay more than the Plan terms required. Instead, they claim that two categories of prescription drugs available under the Plan—which are part of the overall package of thousands of health services and drugs the Plan covers—were too expensive. The first category consists of generic "specialty" drugs. *See, e.g.*, SAC ¶ 5. Generally speaking, specialty drugs are used to treat complex or rare conditions, require special handling or care, or historically were available only at hospitals, doctors' offices, or specialty pharmacies. *See id.* ¶ 78. The Second Amended Complaint challenges the prices of 42 such drugs, but Plaintiffs do not allege that they personally were prescribed or paid for any of them. *See, e.g.*, *id.* ¶¶ 99–118, 208–40.

The second category consists of generic "non-specialty" drugs. *See, e.g.*, *id.* ¶ 6. The Second Amended Complaint challenges the prices of 15 such drugs, out of

the thousands of generic non-specialty drugs available through the Plan. It alleges that Ms. Lewandowski was prescribed 14 of these drugs, while Mr. Gregory was prescribed one. *Id.* ¶¶ 126–27, 234–40.

While Ms. Lewandowski and Mr. Gregory allege they overpaid for generic drugs by approximately $210 and $10, respectively, those amounts were dwarfed by the benefits they received. Ms. Lewandowski received approximately $168,000 worth of benefits paid by J&J for 2022, $198,000 for 2023, and $89,000 for 2024. Ex. D, Decl. ¶ 8. Ms. Lewandowski reached the $3,500 maximum out-of-pocket limitation in each year she participated in the Plan, except that in 2023 she allegedly paid only about $980 thanks to a third-party copay assistance card. *Id.* ¶ 7; SAC ¶¶ 217–29. As a retiree, Mr. Gregory has received benefits paid by J&J for himself and his family members worth approximately $10,000 in 2020 (from October through December), $56,000 in 2021, $28,000 in 2022, $107,000 in 2023, $117,000 in 2024, and $14,000 in 2025 (through March). Ex. D, Decl. ¶ 17. In contrast, he has paid approximately $1,200, $8,900, $4,300, $6,300, $5,300, and $1,100, respectively, for benefits in those years. *Id.*

E. The prior dismissal order.

Ms. Lewandowski filed this putative class action in February 2024 and filed a First Amended Complaint in May 2024. Counts One and Two of the First Amended Complaint were essentially identical claims for breach of the fiduciary

duty of prudence under two provisions of ERISA, 29 U.S.C. §§ 1104 and 1132(a)(2)–(3). Both were based on the theory that Defendants failed to negotiate lower prices for certain generic drugs—a small subset of the prescription drugs available through the Plan, and an even smaller subset of healthcare services covered by the Plan. Dkt. 44 ¶¶ 5–6, 230–35.

This Court dismissed both claims for lack of standing. Ms. Lewandowski claimed she was injured because she allegedly paid higher premiums and higher out-of-pocket expenses for prescription drugs. Dkt. 70 ("MTD Order") at 7. The Court held that the "higher premiums" theory was too speculative to show an Article III injury because Ms. Lewandowski provided no "allegation or evidence of premiums on other plans or that Defendants' specific conduct resulted in the higher premiums." *Id.* at 9. The Court also rejected the "out-of-pocket" theory because Ms. Lewandowski "reached her prescription drug cap for each year." *Id.* at 10–11. "Even if Defendants were to reimburse Plaintiff for her out-of-pocket costs on a given drug," the Court said, those funds would be owed to the Plan—not to Ms. Lewandowski—"to reimburse it for its expenditures on *other* drugs that same year." *Id.* at 11. Because the Court dismissed Counts One and Two for lack of standing, it did not reach Defendants' arguments that those claims should be dismissed for failure to state a claim. *Id.*

The Court declined to dismiss Count Three, which involves an alleged failure to comply with ERISA's requirement to provide certain documents to Ms. Lewandowski upon request. *Id.* at 13–15. That claim—asserted on behalf of Ms. Lewandowski only, not a putative class—remains pending and, in deference to this Court's earlier ruling, is not challenged in this motion.

F. The Second Amended Complaint.

The only material changes in the Second Amended Complaint concern Counts One and Two, which still assert that Defendants allowed excessive prices for two categories of prescription drugs. The Second Amended Complaint adds Mr. Gregory as a plaintiff, along with new allegations about premiums, out-of-pocket expenses, and a single additional drug Mr. Gregory purchased. For example, it provides information about Ms. Lewandowski's alleged use of a copay assistance card to meet her maximum out-of-pocket responsibility in 2023, and cites studies unrelated to the Plan purportedly showing that "premiums will increase when plans overspend on prescription drugs." SAC ¶¶ 195, 198–205, 223–29. But the essence of Counts One and Two—and the core legal defects underlying them—remain the same.

ARGUMENT

I. Plaintiffs lack Article III standing to pursue their claims for breach of fiduciary duty.

Plaintiffs must establish standing to pursue each of their claims. MTD Order at 6 (citing *TransUnion v. Ramirez*, 594 U.S. 413, 423 (2021), and *FW/PBS, Inc. v. Dallas*, 493 U.S. 215, 231 (1990)). There are two kinds of challenges to Article III standing: facial and factual. *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977). A facial challenge contests the sufficiency of the pleadings, while a factual challenge, like the one Defendants are asserting here, "concerns the actual failure of a plaintiff's claims to comport factually with the jurisdictional prerequisites" of Article III. *Constitution Party of Pa. v. Aichele*, 757 F.3d 347, 358 (3d Cir. 2014) (quoting *CNA v. United States*, 535 F.3d 132, 139 (3d Cir. 2008) (brackets omitted)). In assessing a factual challenge to standing, courts "review evidence outside the pleadings" and "make factual findings." *CNA*, 535 F.3d at 145.

To meet Article III's standing requirements, Plaintiffs must show that they (i) suffered an "injury in fact" that is (ii) "fairly traceable" to the challenged conduct, and (iii) likely to be "redressed" by a favorable judicial decision. *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 244 (3d Cir. 2012) (citation omitted); *see also* MTD Order at 6. Injury-in-fact, the "[f]irst and foremost" of these elements, requires a "concrete and particularized"

injury that is "actual or imminent, not conjectural or hypothetical." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338–39 (2016) (citations omitted).

Under *Thole v. U.S. Bank N.A.*, participants in a defined benefit plan where benefits are contractually fixed and "will not change, regardless of how well or poorly the plan is managed," generally lack standing to challenge fiduciaries' management of the plan if they received all of their benefits. 590 U.S. 538, 543 (2020). Plaintiffs do not dispute that they received all of their promised benefits. As a result, they must show that that Defendants caused some other injury. *See* MTD Order at 8–11 (citing *Knudsen v. MetLife Grp., Inc.*, 117 F.4th 570, 573, 578–79 (3d Cir. 2024)). But as explained below, neither their "higher premiums" theory nor their "out-of-pocket" theory supports Article III standing.

A. Plaintiffs' premium allegations do not establish Article III standing.

1. Setting premiums is a non-fiduciary function that cannot support standing for fiduciary claims.

Plaintiffs allege that because annual premiums are based in part on the expected cost of covered healthcare services and drugs, the "excessive" costs of a small fraction of drugs led J&J to set higher premiums in later years for Plan beneficiaries overall. *See, e.g.*, SAC ¶¶ 197–207. But J&J's decision-making on premiums is a non-fiduciary function; it cannot support standing for the fiduciary duty claims.

As relevant here, an entity is a fiduciary only "to the extent" it exercises certain discretionary authority or control over management of a plan. 29 U.S.C. § 1002(21)(A). In other words, "fiduciary status is not an all or nothing concept." *Santomenno v. John Hancock Life Ins. Co. (U.S.A.)*, 2013 WL 3864395, at *4 (D.N.J. July 24, 2013), *aff'd*, 768 F.3d 284 (3d Cir. 2014). The "threshold question" is whether the defendant was "acting as a fiduciary (that is, . . . performing a fiduciary function) when taking the action subject to complaint." *Pegram v. Herdrich*, 530 U.S. 211, 226 (2000).

Decisions about plan *design*—like what services to cover, and what portion of those services will be paid by plan participants in the form of premiums—are not fiduciary acts. *Lockheed Corp. v. Spink*, 517 U.S. 882, 890 (1996). Instead, when plan sponsors make decisions about plan design, they are acting in a role "analogous to the settlors of a trust." *Id.* Matters of plan design include decisions about "the form or structure of the Plan," "who is entitled to receive Plan benefits," and "in what amounts." *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 444 (1999).

The annual setting of premium amounts is a classic "plan design" decision. *See, e.g.*, *Bator v. Dist. Council 4*, 972 F.3d 924, 932 (7th Cir. 2020) ("setting the contribution rates" is a settlor function); *Hannan v. Hartford Fin. Servs., Inc.*, 2016 WL 1254195, at *2–3 (D. Conn. Mar. 29, 2016) (defendant was "not a fiduciary with respect to negotiation of the Plan premiums"), *aff'd*, 688 F. App'x 85 (2d Cir.

2017); *Argay v. Nat'l Grid USA Serv. Co.*, 503 F. App'x 40, 42 (2d Cir. 2012) ("Defendants did not act in a fiduciary capacity in setting premiums"). When a plan sponsor sets healthcare premiums, it is deciding "the terms of a plan" and "in what amounts" to provide benefits. *Hughes*, 525 U.S. at 444–45. ERISA imposes no obligation to set premiums at any particular level, or to pass along any savings in healthcare expenditures in one year in the form of premium reductions in subsequent years.

Because setting premiums is a non-fiduciary function, Plaintiffs cannot base standing for their fiduciary claims on allegedly higher premiums. That was one reason the analogous claims in *Navarro* were dismissed. The plaintiffs in *Navarro* claimed they had standing because they overpaid for prescription drugs, which in turn allegedly prompted their employer to raise premiums. 2025 WL 897717, at *5, *9. The court rejected this domino theory of harm because the plan gave the defendant "sole discretion" to set premiums. *Id.* at *9. The same is true of the J&J Plan. *See* Ex. A, Plan Doc. § 4.01 ("The Sponsor shall establish each year the amount of Participant contributions . . ."); *see also* SAC ¶ 194; Ex. D, Decl. ¶ 2.

2. The "higher premiums" theory is speculative.

Plaintiffs' "higher premiums" theory cannot create Article III standing for an additional reason: It is speculative. This Court held as much in dismissing the prior

complaint, MTD Order at 9, and the Second Amended Complaint does not fix this deficiency.

Plaintiffs assume that lower costs for 57 of the thousands of prescription drugs covered by the Plan would have led to lower premiums for the Plan as a whole in subsequent years, but this is conjecture. Many factors beyond the costs of a handful of drugs—administrative expenses, non-drug medical costs, the costs of other prescription drugs and categories of drugs, and non-cost factors, to take a few examples—can influence the amount of premiums set each year. *See Navarro*, 2025 WL 897717, at *9 (listing factors "having nothing to do with prescription drug benefits," such as "whether a participant obtains coverage for her spouse or children in addition to herself"); Ex. D, Decl. ¶ 2. No agreement or formula governs the setting of premiums, which are set each year by a company committee. Ex. D, Decl. ¶¶ 2–3. Plaintiffs allege that J&J's premiums were set at a "consistent ratio" of projected costs, SAC ¶¶ 196–97, but their own graph shows that premiums were *not* set at a consistent ratio of projected costs; premiums as a percentage of costs varied over time. *Id.* ¶ 196.

Even if Plaintiffs' allegation were accurate, they would be irrelevant. If Plan costs had been lower, the Plan could have charged the same amounts, and it is speculation to claim otherwise. Ex. A, Plan Doc. § 4.01. As another court noted in dismissing essentially the same ERISA claims, "it is speculative that the allegedly

excessive fees the Plan paid to ESI 'had any effect at all' on Plaintiffs' contribution rates and out-of-pocket costs for prescriptions." *Navarro*, 2025 WL 897717, at *9 (quoting *Knudsen*, 117 F.4th at 582).

Other courts, including the Third Circuit, have rejected similar theories as speculative. For example, in *Horvath v. Keystone Health Plan East, Inc.*, 333 F.3d 450 (3d Cir. 2003), the defendants allegedly caused plaintiff's employer to overpay for health benefits, which allegedly led the employer to provide fewer benefits and lower salaries. *Id.* at 453, 457. The Third Circuit rejected that theory as "too speculative." *Id.* at 457. The theory Plaintiffs propose here is no less speculative. *Accord Navarro*, 2025 WL 897717, at *9.

More recently, in *Knudsen v. MetLife Group, Inc.*, 2023 WL 4580406 (D.N.J. July 18, 2023), *aff'd*, 117 F.4th 570 (3d Cir. 2024), plaintiffs claimed that defendants' fiduciary breaches harmed them by inflating their premiums (and out-of-pocket costs), but the Third Circuit rejected that theory as speculative. *Id.* at *5–6; 117 F.4th at 573, 581–82. The Third Circuit explained that a complaint must plausibly allege that the challenged conduct was the "but-for cause" of higher premiums, such as by alleging "in what years" and "by how much" premiums increased, or how premiums are calculated "under the Plan documents." *Knudsen*, 117 F.4th at 581–82. "Allegations of this sort are necessary" to plead Article III standing, *id.* at 582, but the Second Amended Complaint is entirely devoid of

them. When dismissing the earlier iteration of Counts One and Two, this Court rightly described *Knudsen* as "controlling and dispositive" with respect to the "higher premium" theory. MTD Order at 9.

As in the First Amended Complaint, the allegations in the Second Amended Complaint are indistinguishable from those found wanting in *Knudsen*. Plaintiffs still ignore the many factors that influence premiums, such as non-drug medical costs and the plan sponsor's discretion. *See Knudsen*, 117 F.4th at 582. Plaintiffs reproduce the same graph that appeared in the First Amended Complaint, purportedly (but not actually) showing that premiums mirrored projected costs, and add an allegation that, based on the graph, Defendants expected premiums to equal "17–18% of overall Plan healthcare costs." SAC ¶¶ 195–96. But those allegations provide no more certainty than the allegation in *Knudsen* that premiums were generally set at 30% of projected costs. 117 F.4th at 574. In both cases, the assumption that premiums would have been lower if projected costs had been lower is too speculative to confer standing. *See* MTD Order at 9; *accord Navarro*, 2025 WL 897717, at *9 (applying *Knudsen* and rejecting the same "higher premiums" theory).

Finally, the Second Amended Complaint adds allegations about studies supposedly showing that "employee contributions in the form of premiums will increase when plans overspend on prescription drugs." SAC ¶¶ 198–205. But as

even Plaintiffs admit, this theory requires "holding all else constant," *see id.* ¶ 204—an impossibility given the size of the Plan, the innumerable inputs that affect premiums, and the plan sponsor's discretion to change those premiums. *See* MTD Order at 9 (rejecting speculative assertions about higher premiums under *Finkelman v. NFL*, 810 F.3d 187, 201 (3d Cir. 2016)).

B. Plaintiffs' out-of-pocket cost allegations do not establish standing.

1. The out-of-pocket theory is speculative.

Plaintiffs' second theory of standing is that the alleged fiduciary breaches increased their out-of-pocket costs. SAC ¶ 141. This theory too rests on speculation, as *Navarro* found:

> Plaintiffs' theory of redressability stumbles on the same obstacle: Wells Fargo's "sole discretion" to set participant contribution rates. . . . Simply put, while Plaintiffs' requested relief *could* result in lower contribution rates and out-of-pocket costs, there is no guarantee that it *would*, and "pleadings must be something more than an ingenious academic exercise in the conceivable" to meet the standing threshold.

2025 WL 897717, at *10 (citing *United States v. Students Challenging Regulatory Agency Procedures*, 412 U.S. 669, 688 (1973)). In other words, Plaintiffs' "out-of-pocket" theory of standing ignores the plan sponsor's discretion to set premiums and participant contributions levels, as well as the many factors unrelated to the prices of a few prescription drugs that impact participant out-of-pocket costs. *See id.* at *9 (dismissing complaint for lack of standing because, in relevant part, "it is

speculative that the allegedly excessive fees the Plan paid to ESI" affected "out-of-pocket costs for prescriptions").

As the *Navarro* court explained, "selective allegations regarding the markups on a subset of prescription drugs in the Plan's formulary, which itself represents only a subset of the total benefits whose costs Plan participants' contributions may be used to cover, are not sufficient to establish a causal connection between Plaintiffs' increased costs and ESI's administrative fees." 2025 WL 897717, at *9 (citations omitted). For instance, Ms. Lewandowski alleges that she overpaid a total of $210 on two prescriptions in 2023—in a year when she received Plan benefits with a value of more than $200,000. SAC ¶¶ 141, 218–29; Ex. D, Decl. ¶ 8. Mr. Gregory claims he overpaid about $10 for one drug in 2024—in a year when he received more than $121,000 worth of benefits for himself and his family members. SAC ¶¶ 141, 235–37; Ex. D, Decl. ¶ 17. Under these circumstances, it is speculative to conclude that Defendants' administration of the Plan somehow "harmed" Plaintiffs, including because the Plan may have provided savings on other drugs or medical services Plaintiffs received that outweighed Plaintiffs' modest alleged "overpayments" for certain individual drugs. Because Plaintiffs offer nothing but speculation to "fill in the necessary inferential gaps" to jump from isolated alleged overpayments to an overall increase in out-of-pocket costs, they lack standing. *Knudsen*, 117 F.4th at 582.

2. Ms. Lewandowski's "out-of-pocket" theory fails for additional reasons.

In granting Defendants' prior motion to dismiss, the Court ruled that Ms. Lewandowski's alleged out-of-pocket injury is not redressable because she met her $3,500 maximum out-of-pocket limit each year she participated in the Plan. As a result, "[e]ven if Defendants were to reimburse Plaintiff for her out-of-pocket costs on a given drug," those funds would be owed to the Plan "to reimburse it for its expenditures on *other* drugs that same year." MTD Order at 11. Ms. Lewandowski has amended her allegations in an effort to address this deficiency by arguing, oddly, that the fact that she received hundreds of thousands of dollars in benefits while managing to pay only about $980 out of pocket in 2023—far less than the $3,500 cap—caused her injury. But her allegations still fail to show Article III standing, for three reasons.

First, the Second Amended Complaint asserts that notwithstanding the $3,500 out-of-pocket limit, Ms. Lewandowski actually paid only "$979.57 in out-of-pocket [expenses] in 2023" thanks to a copay assistance card—a discount provided by a third-party drug manufacturer. SAC ¶¶ 228–29. She claims that but for Defendants' challenged conduct, she would have paid only $769.57 ($210 less) given the way the copay assistance card worked. *Id.* ¶¶ 213, 220–29. But an injury is not "fairly traceable" to a defendant if it arises from the "independent action of some third party not before the court," *Lujan v. Defs. of Wildlife*, 504 U.S. 555,

560 (1992) (cleaned up), or a plaintiff's "purely voluntary decision" not attributable to a defendant, *Campeau v. Soc. Sec. Admin.*, 575 F. App'x 35, 38 (3d Cir. 2014). The fact that a third party apparently voluntarily reimbursed or chose to assume some portion of Ms. Lewandowski's copayment does not make her alleged injury fairly traceable to Defendants.

Second, Defendants' alleged failure to let Ms. Lewandowski use a copay assistance card to offset more of her out-of-pocket maximum is not a concrete, cognizable injury. This supposed injury does not "bear[] a close relationship to a harm traditionally recognized by American courts." *See Barclift v. Keystone Credit Servs., LLC*, 93 F.4th 136, 145–46 (3d Cir.), *cert. denied*, 145 S. Ct. 169 (2024). The Plan was not required to credit the copay assistance card payment toward Ms. Lewandowski's out-of-pocket maximum at all. Ex. D, Decl. ¶ 11. Ms. Lewandowski therefore cannot establish standing by claiming that she did not receive as much of a discretionary benefit—the counting of third-party copay assistance funds towards her out-of-pocket maximum—as she would have liked. Her argument reflects the Second Amended Complaint's attempt to manufacture financial harm while downplaying ways the Plan saved her and other participants money.

Third, Ms. Lewandowski argues she was injured despite exceeding the maximum out-of-pocket limit because she was "forced" to pay out-of-pocket costs

"sooner than she otherwise would have." SAC ¶ 231. But "accepting the lost time value of money as a cognizable constitutional injury is far from well established." *Taylor v. FAA*, 351 F. Supp. 3d 97, 102–03 (D.D.C. 2018). The Third Circuit has never found it sufficient, and other courts have confirmed that "conclusory proclamations" about "the lost time value of money" are not enough to show standing. *Id.*; *see also, e.g.*, *Tokyo Gwinnett, LLC v. Gwinnett County, Ga.*, 940 F.3d 1254, 1264 (11th Cir. 2019). It is likewise not enough here.

C. Plaintiffs do not allege they paid for any generic specialty drugs or were harmed by other challenged conduct.

A plaintiff who was unaffected by a defendant's conduct does not have standing to challenge that conduct. Instead, "[o]nly those plaintiffs who have been *concretely harmed*" have standing. *TransUnion*, 594 U.S. at 427; *see also, e.g.*, *Huber v. Simon's Agency, Inc.*, 84 F.4th 132, 152 (3d Cir. 2023) ("[R]egardless of whether the defendant violated the law, the plaintiff must establish that she herself suffered a concrete harm.").

Under those principles, Plaintiffs lack standing to challenge the prices of generic specialty drugs, a category of drug on which the majority of their allegations rest but which they do not claim to have actually bought. The Second Amended Complaint claims that 42 generic specialty drugs were too expensive, *see* SAC ¶¶ 105–18, but it does not allege that either Plaintiff ever was prescribed or purchased any of those drugs. Plaintiffs therefore did not suffer an injury-in-fact

related to prices for those drugs. *Finkelman*, 810 F.3d at 195 (affirming dismissal for lack of Article III standing because plaintiff "never purchased" the allegedly overpriced tickets at issue).

Plaintiffs' other theories of imprudence fail for similar reasons. The Second Amended Complaint asserts that Defendants mismanaged the Plan by "agreeing to steer beneficiaries toward Express Scripts' mail-order pharmacy, Accredo," SAC ¶ 131, and "failing to disincentivize the use of high-priced branded drugs on the Plans' formulary in favor of lower-priced generics," *id.* ¶ 137. But Plaintiffs do not allege that they were ever "steered" toward Accredo, or that they ever used a branded drug when a lower-priced generic version was available. They lack standing to assert these theories. *TransUnion*, 594 U.S. at 427–28.

II. Counts One and Two fail to state a claim under Rule 12(b)(6) because Plaintiffs do not plausibly allege an imprudent process.

ERISA's duty of prudence turns on "process rather than the results." *McCaffree Fin. Corp. v. ADP, Inc.*, 2023 WL 2728787, at *13 (D.N.J. Mar. 31, 2023). Plaintiffs' allegations must support the inference that Defendants used an imprudent process in choosing ESI as the Plan's pharmacy benefit manager and in negotiating drug prices with that entity. *See, e.g.*, *id.* At a minimum, Plaintiffs must allege facts indicating that the overall package of prescription drugs was unduly expensive compared to those in similarly situated healthcare plans—plans with coverage, access, and service needs similar to those of the J&J Plan. *See Mator v.*

Wesco Distrib., Inc., 102 F.4th 172, 188 (3d Cir. 2024); *Singh v. Deloitte LLP*, 123 F.4th 88, 95–96 (2d Cir. 2024) (holding in the retirement plan context that a plaintiff must establish that other plans are "apple-to-apple" comparators); *Matney v. Barrick Gold of N. Am.*, 80 F.4th 1136, 1148–49 (10th Cir. 2023) (same). Plaintiffs are not entitled to an inference of imprudence "simply from the allegation that a cost disparity exists." *Matney*, 80 F.4th at 1148–49; *see also, e.g.*, *McCaffree*, 2023 WL 2728787, at *14.

Plaintiffs come nowhere close to identifying "apples-to-apples" comparator plans whose plan sponsors made objectively superior decisions. *See Mator*, 102 F.4th at 187. The Second Amended Complaint's selective drug-by-drug comparison does not compare the Plan's overall package of health benefits (or even the narrower subset of prescription drug benefits) with any benchmark. Instead, Plaintiffs ask the Court to infer imprudence based on a cherry-picked subset of results: the prices of 42 generic specialty drugs and 15 generic non-specialty drugs, out of thousands of health services and drugs covered by the Plan. *See* SAC ¶¶ 105–18, 235–40. But the fiduciaries of the Plan negotiate *overall* Plan benefits—both medical and prescription drug benefits—with *all* participants in mind, not a subset who take the small number of drugs whose prices Plaintiffs are challenging. *See Mator*, 102 F.4th at 188; *McCaffree*, 2023 WL 2728787, at *14.

Allegations about the out-of-pocket costs for a select handful of drugs cannot support an inference of imprudence.

The differences between the retirement plans at issue in cases like *Mator* and healthcare plans like the J&J Plan only confirm Plaintiffs' failure to state a claim. Cases like *Mator* arise in the retirement plan context, where plaintiffs challenge the prudence of investment options on a retirement plan's menu. In those cases, however, the plan fiduciaries typically oversee perhaps a dozen or two dozen investment options—a small number of variables that comes nothing close to the thousands of drugs (and medical services) available through the Plan.

While the Second Amended Complaint includes allegations about the practices of a few other companies' health plans, SAC ¶¶ 177–91, none of these allegations suggest that any plan of comparable size, scope, and benefit levels pays less than the J&J Plan for the universe of health services and drugs covered by the Plan, or even for the narrower subset of prescription drugs Plaintiffs challenge. Most of these allegations simply describe measures that may have resulted in cost savings, without any suggestion that any other plan paid less in total, or even per person, than the J&J Plan. For example, Plaintiffs fail to allege that any of the so-called comparators provide equivalent coverage for lower premiums, copay amounts, and maximum out-of-pocket limitations.

Plaintiffs' most specific comparison is to PepsiCo's health plan, which allegedly had lower cost-sharing amounts than the Plan for a small subset of drugs identified in the Second Amended Complaint. SAC ¶ 179. Yet Plaintiffs allege nothing about total plan drug costs, premiums, out-of-pocket limitations, or whether the plan participants received similar access, service, or other benefits under PepsiCo's plan. *See Singh*, 123 F.4th at 97. These omissions prevent the Second Amended Complaint from plausibly supporting an inference of imprudence. *See id.*

Plaintiffs' allegations reflect a variety of alternative approaches taken by other companies' plans without demonstrating that any specific approach is imprudent. Again, there is no suggestion that the other companies' plans had the same level of benefits as the J&J Plan. *See Navarro*, 2025 WL 897717, at *8 n.9 ("Plaintiffs do not allege facts regarding the relative size and scope of those companies' plans."); *see, e.g.*, SAC ¶ 181 (discussing other plan with carve-out for specialty drugs); *id.* ¶ 183 (use of a pass-through PBM). Moreover, none of Plaintiffs' allegations suggest that the measures taken by other companies are consistently and commonly undertaken by prudent fiduciaries. As the *Navarro* court explained, "ESI is one of the 'Big 3' PBMs," so "[e]ven if [J&J] had conducted an 'open RFP process,' as Plaintiffs insist it should have, [SAC ¶ 95], it appears quite plausible that [J&J] still would have selected ESI—as many other

companies evidently have." 2025 WL 897717, at *8 n.9. In short, these allegations fail to provide a meaningful benchmark that would allow this Court to infer that J&J had a defective process.

That failure is especially telling because the Second Amended Complaint suggests that examples of comparable plans that paid less for comparable health benefits (or even for the narrower subset of prescription drug benefits) should be easy to find. In particular, the Second Amended Complaint points to alternative, pass-through PBMs that pass through their costs for prescription drugs and charge only administrative fees for running the whole program. *Id.* ¶ 57. It even points to a few plans that have switched to pass-through PBMs. *Id.* ¶¶ 179–82, 184–89. Yet Plaintiffs never demonstrate that these plans offer a package of benefits comparable to those offered under the J&J Plan at a lower cost.

Finally, Plaintiffs' suggestion of imprudence is implausible under the well-established standards of *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). J&J's fiduciary and corporate interests are aligned to get the best overall deal at a reasonable cost, because J&J bears more than 80% of the cost of prescription drugs and services covered by the Plan. J&J has every incentive to negotiate the best overall deal for Plan services because J&J, not the participants, bears the vast majority of the Plan's expenditures. *Cf. Thole*, 590 U.S. at 545 (employers "are often on the hook for plan shortfalls," so "the last

thing a rational employer wants or needs is a mismanaged [benefits] plan"). Also relevant are the Supreme Court's recent reminders that *Iqbal* and *Twombly* apply with full force in ERISA class actions, that "[a]t times, the circumstances facing an ERISA fiduciary will implicate difficult tradeoffs," and that, in assessing a motion to dismiss in the ERISA context, "courts must give due regard to the range of reasonable judgments a fiduciary may make based on her experience and expertise." *Hughes v. Northwestern Univ.*, 595 U.S. 170, 177 (2022).

Consistent with those incentives and principles, the obvious alternative explanation for the fact that some subset of drugs allegedly have high prices is that those prices were part of the best overall deal Defendants could negotiate for the thousands of drugs covered by the prescription drug program. *See Mator*, 102 F.4th at 184 & n.3 ("[T]he Rules require dismissal when fiduciary defendants offer an alternative explanation for their conduct that is obvious, natural, or simply more likely than the plaintiff's theory of misconduct." (quotation marks omitted)). The sheer number of covered drugs makes drug-by-drug negotiation impracticable. While Plaintiffs need not rule out every possible explanation for challenged prices, they must do more than point to a handful of drugs out of thousands with supposedly excessive costs.

CONCLUSION

The Court should dismiss the Second Amended Complaint, enter judgment against Plaintiffs and in favor of Defendants, and award Defendants any other appropriate relief.

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Respectfully submitted,

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